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EXAMINER	
HUGHES, ALICIA R	
ART UNIT	PAPER NUMBER
1614	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/799,197	FISHBEIN, DON	
	Examiner	Art Unit	
	ALICIA R. HUGHES	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 September 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *30-45 and 47* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *30-45 and 47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1 sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims and Examination

Claims 30-45 and 47 are pending and the subject of this Office Action. Applicants cancelled claim 46 on 08 September 2009.

Applicant's arguments filed on 08 September 2009 has been fully considered but are deemed to be persuasive regarding the previous rejection. Rejections not reiterated from this Office's previous action are hereby withdrawn. The rejections set forth herein constitute the complete set of rejections being applied to the instant application presently.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Priority

Applicant claims priority as early as 05 December 1996, dating back to U.S. Patent Provisional Application No. 60/032,414. A review of each of the aforementioned disclosures failed to yield a teaching of the instantly claimed invention, as amended. Moreover, the newly amended claims give rise of a rejection under 35 U.S.C. §112.1 for new matter. As a result, for prior art purposes, herein, the filing date of this application, 12 March 2004 is considered the relevant date.

Claim Rejections - 35 U.S.C. §112.1

The following is a quotation of the first paragraph of 35 U.S.C. §112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the

> best mode contemplated by the inventor of carrying out his invention.

Claims 30-45 and 47 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant, in his remarks filed on 08 September 2009, amended claim 30, to incorporate the limitation "wherein the weight gained is maintained at least five weeks after discontinuation of oxandrolone administration," which changed the scope of the invention in a manner not previously contemplated. A review of application as filed does not disclose the invention embodied by the present set of claims as a result of the incorporation of this limitation. And if the same is supported, Applicant has failed to draw attention to the page and line numbers in the specification that support its amendment.

In light of the foregoing and absent any express evidence to the contrary, claims 30-45 and 47 as written are rejected, because they contain new matter not supported by the specification. This is a new matter rejection.

Claim Rejection - 35 U.S.C. §102(a)

The following is a quotation of 35 U.S.C. 102(a) which forms the basis for all obviousness rejections set forth in this Office Action:

> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 30, 42-45 and 47 are rejected under 35 U.S.C. 102(a) as being anticipated by Demling, Robert H., "Oxandrolone Induced Lean Mass Gain During Recovery From Severe Burns Is Maintained After Discontinuation of the Anabolic Steroid," *Burns*, Vol. 29, pages 793-797 (2003)[hereinafter referred to as Demling et al"].

Applicant, in independent claim 30 specifies a method of promoting weight gain after weight loss resulting from burn-induced trauma by administering oxandrolone. The claim has been amended to add the limitations that the amount of oxandrolone administered should be capable of promoting weight gain "wherein the weight gained is maintained at least five weeks after discontinuation of oxandrolone administration" (Amended Claim 30 as filed on 08 September 2009.

Demling et al teach that "severe catabolism, resulting in rapid loss of lean body mass, is a well-recognized complication of major burns" (Page 793, Col. 1, lines 1-2) and that "providing … oxandrolone has been shown to significantly increase the rate of restoration of lost body weight and lean mass after burn injury" (Page 793, Col. 1, lines 8-11). Demling et al undertook a study to determine "whether the lean mass and body weight which was regained was maintained 6 months after discontinuation of the oxandrolone" (Page 793, Col. 2, lines 12-15) by studying major burn patients in the recovery phase where attempts to restore lost weight and lean mass are initiated (Page 793, Col. 2, lines 16-19).

Patients in the study were monitored after discharge from an acute burn center for at least one year (Page 794, Col. 1, lines 7-9). The patient population was randomly split into two categories, one receiving optimum nutrition, including protein and exercise and the other receiving optimum nutrition, including protein (Page 795, Figure 2) and exercise supplemented

by the administration of oxandrolone (Page 794, Col. 1, lines 11-17; See also page 795, Table 2). In the course of the study, "[b]i-weekly changes in lean body mass were calculated and compared with changes in lean body mass were calculated and compared with changes in body weight to determine the percent of weight gain which was lean mass (Page 794, Col. 1, last line through Col. 2, lines 1-3). Body composition and body weight were measured at discharge from rehab and again at 6 month post-discharge for all patients and in for oxandrolone patients, again 6 Months after discontinued use (Page 794, Col. 2, lines 4-10). "Oxandrolone was discontinued once ninety percent of the lost body weight had been restored and the patients were at a level of muscular function which allowed for independent daily living activities (Page 797, Col. 1, lines 6-9).

Table 1 of Demling et al does a comparative analysis of post-burn changes in body weight and demonstrates that in weeks 1, 2, 3, and 4, the body weight of patients treated with oxandrolone more than doubled that of patients not so treated (Page 794, Table 1). Based on the data provided, Demling et al concluded that "[t]here was a significant increase in body weight and lean body mass gain in the group receiving oxandrolone compared to the nutrition alone group at all measurement periods during the acute rehabilitation phase (Page 795, Col. 1, lines 6-9). And importantly, "[a]ll restored LBM ["lean body mass"] was retained" (Page 796, Col. 1, lines 12-13).

Demling et al state conclusively, "the addition of an anabolic steroid increases the rate of restoration of lost body weight and lean mass up to four-fold after burns, trauma, infection and other post-catabolic states ... It is anticipated that lean mass that has been regained remains after discontinuation of the anabolic steroid …"(Page 796, Col2, lines 4-10). More specifically, "the

amount of lean mass gained in both groups during the acute rehabilitation period did not change 6 months after discharge, indicating that the large amount of lean mass gained on oxandrolone was maintained after discontinuation" (Page 797, Col. 1, lines 22-26 and last two lines).

With regard to claim 42, as noted prior and referenced on a previous PTO-892 Form, oxandrolone is an anabolic steroid with numerous synonymous chemical names, including 17β-Hydroxy-17α-methyl-2-oxa-5α-androstan-3-one, as disclosed in claim 42 of the present invention. Therefore, oxandrolone as noted by its IUPAC name is met by the disclosure in Demling et al.

In light of the foregoing, claims 30, 42-45 and 47 are clearly anticipated.

Claim Rejection – 35 U.S.C. §103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 30-40 are rejected under 35 U.S.C. 103(a) as being obvious over Demling et al in view of U.S. Patent No. 6,090,799 [hereinafter referred to as "Berger"][1].

The teachings of Demling et al, *supra*, are incorporated herein by reference in their entirety. Demling et al do not disclose, but rather is silent on the dosage amounts of oxandrolone administered and as well, to routes of administration. The same, however, are taught by Berger.

[1] Cited on previous PTO-892 Form.

Berger teaches that "[a]nabolic steroids, as a class, are known to stimulate appetite" (Col. 2, lines 64-65), and furthermore, that oxandrolone, increases protein synthesis (Col. 3, lines 4-5). Berger also teaches that "[i]mproved nutrition is important to individuals with AIDS who have experienced loss of lean body mass" (Col. 2, lines 65-67). Berger also teaches the administration of oxandrolone, in a daily dosage of about 2.5 milligrams ["mg"] to about 80 mg (Abstract; Col. 2, lines 14-18; Col. 3, lines 30-38; Col. 5, lines 41-49). Through the administration of oxandrolone, "[l]oss in muscle mass (wasting) is attenuated, and body weight can be more readily maintained in this manner … revers[ing] weight loss" (Col. 2, lines 1-5; see also, the Example at Col. 7, lines 33-57 – Col. 8, lines 1-24). For purposes of examination herein, the Examiner interprets "reversing weight loss" to be equivalent with weight gain.

Berger also teaches that "[o]xandrolone preferably is administered orally; however, other routes of administration can be utilized as well" (Col. 2, lines 8-9). The Berger invention teaches oxandrolone combined with solid or liquid pharmaceutical carriers and formulated using pharmacologically acceptable excipients, or dissolved or suspended in physiologically acceptable solvents or liquid vehicles for oral, percutaneous, or topical administration (Col. 3, lines 19-25). "Examples of suitable unit dosage forms in accordance with this invention are tablets, pills, powder, packets, wafers, cachets, segregated multiples of any of the foregoing, transdermal patches, aliquots of injectables, and like forms" (Col. 4, 35-39).

Though Berger does not teach the use of anabolic steroids in the treatment of burns, one of ordinary skill in the art would be motivated to modify the teachings of Demling et al by the teachings in Berger to arrive at the instant invention, because both references teach patient

populations that have experienced attenuated exponential wasting due to catabolism that is reversed by the administration of oxandrolone.

In light of the foregoing, and absent any evidence to the contrary, one would conclude that it would have been *prima facie* obvious to one of ordinary skill in the art that the administration of oxandrolone, in the dosages and dosage forms disclosed in the present invention, would be an effective method for promoting weight gain after weight loss for one who experiences loss of lean body mass due to burn-induced trauma.

Claims 30 and 41 are rejected under 35 U.S.C. 103(a) as being obvious over Demling et al in view of U.S. Patent No. 5,434,146 [hereinafter referred to as "Labrie et al"].[2]

The teachings of Demling et al, *supra*, are incorporated herein by reference in their entirety. Demling et al do not disclose, but rather is silent on oxandrolone administered in a sustained release formulation. The same, however, is taught by Labie et al.

Labrie et al teach the administration of certain anabolic steroids, including oxandrolone, in a sustained release formulation (Abstract; Col. 21, lines 17 and 61-68).

One of ordinary skill in the art would be motivated to combine the teachings of Demling et al with the teachings of Labrie et al., due to their overlapping subject matter, most notably the administration of oxandrolone. In view of the foregoing, it would have been *prima facie* obvious to one of ordinary skill in the art that the administration of an effective amount of oxandolone in sustained release formulations would be effective for promoting weight gain after weight loss resulting from burn-induced trauma in a patient.

[2] Cited on previous PTO-892 Form.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alicia Hughes whose telephone number is 571-272-6026. The examiner can normally be reached from 9:00 AM to 5:00 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached at 571-272-0718. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR of Public PAIR. Status information for unpublished

applications is available through Public PAIR only. For information about the PAIR system, see http://pair-direct-uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Alicia R. Hughes/

Examiner, Art Unit 1614

/Ardin Marschel/

Supervisory Patent Examiner, Art Unit 1614